PATENT COOPERATION TREATY

From the
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

To:
GAL EHRLICH
C/O ANTHONY CASTORINA
2001 JEFFERSON DAVIS HIGHWAY
SUITE 207
ARLINGTON, VA 22202

PCT

WRITTEN OPINION

(PCT Rule 66)

Date of Mailing *(day/month/year)*	15 JUN 2006
Applicant's or agent's file reference 02/23560	REPLY DUE within 1 months/days from the above date of mailing

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/IL03/00079	30 January 2003 (30.01.2003)	31 January 2002 (31.01.2002)

International Patent Classification (IPC) or both national classification and IPC

IPC: Please See Continuation Sheet
USPC: 514/2,16;530/300,327,328,329

Applicant

RAMOT AT TEL AVIV UNIVERSITY LTD.

1. This written opinion is the first (first, etc,) drawn by this International Preliminary Examining Authority.

2. This opinion contains indications relating to the following items:

- I ☒ Basis of the opinion
- II ☐ Priority
- III ☒ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- IV ☒ Lack of unity of invention
- V ☒ Reasoned statement under Rule 66.2 (a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☐ Certain defects in the international application
- VIII ☐ Certain observations on the international application

3. The applicant is hereby **invited to reply** to this opinion.

When? See the time limit indicated above. ~~The applicant may, before the expiration of that time limit, request this Authority to grant an extension. See rule 66.2(d).~~

How? By submitting a written reply, accompanied, where appropriate, by amendments, according to Rule 66.3. For the form and the language of the amendments, see Rules 66.8 and 66.9.

Also For an additional opportunity to submit amendments, see Rule 66.4.
For the examiner's obligation to consider amendments and/or arguments, see Rule 66.4 *bis*.
For an informal communication with the examiner, see Rule 66.6

If no reply is filed, the international preliminary examination report will be established on the basis of this opinion.

4. The final date by which the international preliminary examination report must be established according to Rule 69.2 is: 31 May 2004 (31.05.2004) .

Name and mailing address of the IPEA/US
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I. Basis of the opinion

1. With regard to the elements of the international application:*

☒ the international application as originally filed

☒ the description:
pages 1-73, as originally filed
pages NONE, filed with the demand
pages NONE, filed with the letter of _____.

☒ the claims:
pages 74-91, as originally filed
pages NONE, as amended (together with any statement) under Article 19
pages NONE, filed with the demand
pages NONE, filed with the letter of _____.

☒ the drawings:
pages 1-43, as originally filed
pages NONE, filed with the demand
pages NONE, filed with the letter of _____.

☒ the sequence listing part of the description:
pages 1-29, as originally filed
pages NONE, filed with the demand
pages NONE, filed with the letter of _____.

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.
These elements were available or furnished to this Authority in the following language _____ which is:

☐ the language of a translation furnished for the purposes of international search (under Rule23.1(b)).

☐ the language of publication of the international application (under Rule 48.3(b)).

☐ the language of the translation furnished for the purposes of international preliminary examination(under Rules 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the written opinion was drawn on the basis of the sequence listing:

☒ contained in the international application in printed form.

☒ filed together with the international application in computer readable form.

☐ furnished subsequently to this Authority in written form.

☐ furnished subsequently to this Authority in computer readable form.

☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. ☐ The amendments have resulted in the cancellation of:

☐ the description, pages NONE _____

☐ the claims, Nos. NONE _____

☐ the drawings, sheets/~~fig~~ NONE _____

5. ☐ This opinion has been drawn as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

* *Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this opinion as "originally filed."*

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III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The question whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application,

☒ claims Nos. 17-21, 27-69, 81-90, 101-155

because:

☐ the said international application, or the said claim Nos. _____ relate to the following subject matter which does not require international preliminary examination *(specify)*:

☐ the description, claims or drawings *(indicate particular elements below)* or said claims Nos. _____ are so unclear that no meaningful opinion could be formed *(specify)*:

☐ the claims, or said claims Nos. _____ are so inadequately supported by the description that no meaningful opinion could be formed.

☒ no international search report has been established for said claims Nos. 17-21,27-69,81-90 and 101-155.

2. A written opinion cannot be drawn due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:

☐ the written form has not been furnished or does not comply with the standard.

☐ the computer readable form has not been furnished or does not comply with the standard.

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IV. Lack of unity of invention

1. In response to the invitation (Form PCT/IPEA/405) to restrict or pay additional fees the applicant has:
   - ☒ restricted the claims.
   - ☐ paid additional fees.
   - ☐ paid additional fees under protest.
   - ☐ neither restricted nor paid additional fees.

2. This Authority found that the requirement of unity of invention is not complied with for the following reasons and chose, according to Rule 68.1, not to invite the applicant to restrict or pay additional fees:

3. Consequently, the following parts of the international application were the subject of international preliminary examination in establishing this opinion:
   - ☐ all parts.
   - ☒ the parts relating to claims Nos. 1-16,22-26,70-80,91-100(partialy,SEQ ID NO: 4).

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V. Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. STATEMENT

Novelty (N)	Claims Please See Continuation Sheet	YES
	Claims Please See Continuation Sheet	NO
Inventive Step (IS)	Claims Please See Continuation Sheet	YES
	Claims Please See Continuation Sheet	NO
Industrial Applicability (IA)	Claims Please See Continuation Sheet	YES
	Claims Please See Continuation Sheet	NO

2. CITATIONS AND EXPLANATIONS
Please See Continuation Sheet

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Supplemental Box
(To be used when the space in any of the preceding boxes is not sufficient)

TIME LIMIT:
The time limit set for response to a Written Opinion may not be extended. 37 CFR 1.484(d). Any response received after the expiration of the time limit set in the Written Opinion will not be considered in preparing the International Preliminary Examination Report.

Continuation of IPC:
A01N 37/18;A61K 38/00(2006.01),38/04(2006.01)
A01N 37/18(2006.01);A61K 38/00(2006.01),38/04(2006.01)

V.1. Reasoned Statements:
The opinion as to Novelty was positive (Yes)with respect to claims 3-7, 11-15, 22-26, 71, 72, 76, 77, 78, 80, 95-100
The opinion as to Novelty was negative (No) with respect to claims 1, 2, 8, 9, 10, 70, 73-75, 79, and 91-94
The opinion as to Inventive Step was positive (Yes)with respect to claims 3-7, 11-15, 22-26, 71, 72, 76, 77, 78, 80, 95-100
The opinion as to Inventive Step was negative(NO) with respect to claims 1, 2, 8, 9, 10, 70, 73-75, 79, and 91-94
The opinion as to Industrial Applicability was positive (YES) with respect to claims 1-16, 22-26, 70-80, 91-100
The opinion as to Industrial Applicability was negative(NO) with respect to claims NONE

V. 2. Citations and Explanations:
Claims 1, 2, 8, 9, and 10 lack novelty under PCT Article 33(2) as being anticipated by the following references:

Kapurniotu et al. (Accession AAW93015) teach a peptide comprising an amino acid sequence of at least 3 amino acid residues and less than 15 amino acid residues including an amino acid sequence of SEQ ID NO: 7, where said amino acid sequence includes polar uncharged residues of serine and asparagine, two serine residues at the C-terminus, and the beta-breaker glycine residue (see alignment).

Mosselman et al. (Accession S04016) teach a peptide comprising an amino acid sequence of at least 3 amino acid residues and less than 15 amino acid residues including an amino acid sequence of SEQ ID NO: 7, where said amino acid sequence includes polar uncharged residues of serine and asparagine, two serine residues at the C-terminus, and the beta-breaker glycine residue (see alignment).
Thus, the reference teachings anticipate the claims.

Claims 70, 73-75, 79, and 91-94 lack an inventive step under PCT Article 33(3) as being obvious over Kapurniotu et al. (Accession AAW93015) or Mosselman et al. (Accession S04016) in view of US Patent 6,303,567 (Findeis et al.).

US Patent 6,303,567 (Findeis et al.) teach pharmaceutical compositions for treating or preventing amyloid-associated diseases comprising compounds and a pharmaceutically acceptable carrier or diluent (see entire publication). US Patent 6,303,567 does not teach the pharmaceutical composition recited in claims 70, 73-75, 79, and 91-94.

The teachings of Kapurniotu et al. (Accession AAW93015) and Mosselman et al. (Accession S04016) have been stated above.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the pharmaceutical compositions of US Patent 6,303,567 such that the pharmaceutical composition is formulated with the peptides taught by Kapurniotu et al. (Accession AAW93015) and Mosselman et al. (Accession S04016). One of ordinary skill in the art would be motivated to do this for the purposes of having a pharmaceutical composition that can be used in treating or preventing amyloid-associated diseases.

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Supplemental Box
(To be used when the space in any of the preceding boxes is not sufficient)

Claims 3-7, 11-15, 22-26, 71, 72, 76, 77, 78, 80, 95-100 meet the criteria set out in PCT Article 33(2) (3), because the prior art does not teach or fairly suggest a peptide comprising an amino acid sequence of SEQ ID NO: 4 and a pharmaceutical composition comprising said peptide.

Claims 1-16, 22-26, 70-80, 91-100 the criteria set out in PCT Article 33(4), and thus has industrial applicability because the subject matter claimed can be made or used in industry.

---------- NEW CITATIONS ----------